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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,527	05/29/2003	Sean Farmer	19374-503	8102

30623 7590 04/03/2006

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EXAMINER	
PRATS, FRANCISCO CHANDLER	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/424,527	FARMER ET AL.	
	Examiner	Art Unit	
	Francisco C. Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *26-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-10-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-50 are presented for examination.

Election/Restrictions

Applicant's election without traverse of the group I invention, claims 1-25, and the species wherein (a) the microorganism is *Bacillus coagulans,* and (b) the oligosaccharide is FOS, in the reply filed on January 12, 2006, is acknowledged.

Claims 26-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As noted immediately above, election was made **without** traverse in the reply filed on January 12, 2006.

Claims 1-25 are examined on the merits to the extent they read on the elected species.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/048,452, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, the earlier provisional application does not mention the bifidogenic oligosaccharides recited in claims 12-18. Thus, claims 12-18 have an effective filing date of June 3, 1998, the filing date of the international stage of this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating bacterial gastrointestinal infections, does not reasonably provide enablement for preventing bacterial gastrointestinal infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Specifically, the claimed recitation of "preventing" bacterial gastrointestinal infections encompasses the prevention of any and all infections in the gastrointestinal tract, and in every instance. Gastrointestinal infections are caused by a numerous organisms having widely varying properties, not just the *Clostridium* species which are the focus of the disclosure as filed. Examples include pathogenic strains of *E. coli*, which are known to cause severe diarrhea. Thus, while applicant's disclosure demonstrates that administration of *B. coagulans* reduces the numbers of certain pathogenic and/or undesirable intestinal bacteria, the specification as filed fails to enable the full scope of the "preventing" language, which, requires prevention of any and all infections in the gastrointestinal tract, and in

every instance. One of skill in the art would therefore have to undertake essentially a trial and error process, with no reasonable expectation of success provided from the as-filed specification to determine how to practice the full scope of the invention as now claimed. A holding of non-enablement is therefore clearly proper. In sum, undue experimentation would be required to practice the full scope of the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United

States and was published under Article 21(2) of such treaty in the English language.

Claims 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Cavadini et al (U.S. Pat. 5,968,569).

As discussed above, claims 12-18 have an effective filing date of June 3, 1998, which is after the December 23, 1997 filing date of the Cavadini patent. Cavadini discloses the preparation of food products, including infant cereals (column 2, line 13), which contain probiotic microorganisms which can be *B. coagulans* (column 3, line 14), and which may contain fructooligosaccharides (column 4, line 1) as a soluble fiber component. The compositions are disclosed as being useful in the treatment and inhibition of intestinal pathogens such as *C. perfringens* and *H. pylori* in humans (see column 1, lines 16-23; see also column 6, lines 50-67). Because the reference discloses administering the claimed ingredients in the treatment of diseases encompassed by the claims, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavadini et al (U.S. Pat. 5,968,569).

As discussed above, Cavadini discloses administering the claimed ingredients in the treatment of diseases encompassed by the claims, and is therefore considered to anticipate claims 12 and 13. Moreover, even if one of ordinary skill did not immediately envisage the claimed treatment method from Cavadini's disclosure, Cavadini clearly provides motivation for

practicing the subject matter recited in claims 12 and 13 by disclosing that the claimed ingredients were suitable in methods of treating the claimed disorder.

Cavadini differs from the claims in that Cavadini does not disclose the specific polymer length of the fructooligosaccharides administered therein, nor does Cavadini disclose administration of the specific dosages recited in the claims. However, the artisan of ordinary skill at the time of applicant's invention clearly would have recognized that by varying the amount of the fiber component used in the therapeutic methods of Cavadini, one would have affected the result of the therapeutic methods. Thus, the claimed selection of a specific dosage of the soluble fiber component used in the therapeutic methods of Cavadini must be considered an optimization of a result-effective parameter, and therefore obvious under § 103(a). Similarly, in view of Cavadini's generic disclosure of the suitability of fructooligosaccharides in the disclosed treatment methods, the selection of nearly all polymer lengths falling within Cavidini's generic disclosure, must be considered obvious, the artisan of ordinary skill clearly being motivated to use molecules falling within the disclosed genus. Thus, absent some demonstration of an unexpected result coming from the claimed dosage and size of

fructooligosaccharides, claims 12-18 must be considered obvious under § 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 and 19-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of U.S. Patent No. 6,461,607, and claims 1-10 of U.S. Patent No. 6,849,256. Although the conflicting claims are not identical, they are not patentably

distinct from each other because both sets of patented claims recite the treatment and or inhibition of gastrointestinal disorders in mammals and/or animals, by administering the same organism, *B. coagulans*. In view of the generic claims encompassing the presently claimed treatment of humans, as well as the recognition that humans, including infants, suffer from bacterial infections, the artisan of ordinary skill clearly would have been motivated to have treated humans using the patented claims' methods. Moreover, the artisan of ordinary skill at the time of applicant's invention clearly would have recognized that by varying the amount of the therapeutic agent used in the therapeutic methods of the patented claim, one would have affected the result of the therapeutic methods. Thus, the claimed selection of a specific dosages, or cell amounts, of the therapeutic component used in the therapeutic methods of the patented claims must be considered an optimization of a result-effective parameter, and therefore obvious over the patented claims. Similarly, the use of known orally acceptable vehicles recited in the claims under examination herein must be considered obvious, in view of the patented claims' disclosure that the therapeutic agents may be administered orally. A terminal disclaimer is clearly required.

Claims 12-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of U.S. Patent No. 6,461,607 and claims 1-10 of U.S. Patent No. 6,849,256, in view of Cavadini et al (U.S. Pat. 5,968,569). Specifically, as discussed above, the claims under examination are considered obvious over the therapeutic methods recited in the claims of the '607 and '256 patents. Claims 12-18 under examination herein differ from the patented claims in that claims 12-18 recite the additional administration of fructooligosaccharides. However, as discussed above, Cavadini discloses the suitability of administering fructooligosaccharides in therapeutic methods wherein *B. coagulans* is administered to treat bacterial infections of the gastrointestinal system. Moreover, as also discussed above, the determination of suitable dosages and particular species of that therapeutic agent would have been well within the purview of the artisan of ordinary skill. Thus, claims 12-18 must also be considered obvious variants of the therapeutic methods recited in the patented claims. A terminal disclaimer is properly required.

Claims 1-11 and 19-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as

being unpatentable over claims 25-35 of copending Application No. 11/005,897. Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic claims in the copending application encompass the presently claimed treatment of humans. Thus, based on the recognition that humans, including infants, suffer from bacterial infections, the artisan of ordinary skill clearly would have been motivated to have treated humans using the methods recited in the copending claims. Moreover, the artisan of ordinary skill at the time of applicant's invention clearly would have recognized that by varying the amount of the therapeutic agent used in the therapeutic methods of the patented claim, one would have affected the result of the therapeutic methods. Thus, the claimed selection of specific dosages, or cell amounts, of the therapeutic component used in the therapeutic methods of the copending claims must be considered an optimization of a result-effective parameter, and therefore obvious over the patented claims. Similarly, the use of known orally acceptable vehicles recited in the claims under examination herein must be considered obvious, in view of the copending claims' disclosure that the therapeutic agents may be administered orally. A terminal disclaimer is clearly required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 12-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-35 of copending Application No. 11/005,897 in view of Cavadini et al (U.S. Pat. 5,968,569).

Specifically, as discussed above, the claims under examination are considered obvious over the therapeutic methods recited in the claims of copending Application No. 11/005,897. Claims 12-18 under examination herein differ from the copending claims in that claims 12-18 recite the additional administration of fructooligosaccharides. However, as discussed above, Cavadini discloses the suitability of administering fructooligosaccharides in therapeutic methods wherein *B. coagulans* is administered to treat bacterial infections of the gastrointestinal system. Moreover, as also discussed above, the determination of suitable dosages and particular species of that therapeutic agent would have been well within the purview of the artisan of ordinary skill. Thus, claims 12-18 must also be considered obvious variants of the therapeutic methods recited

in the copending claims. A terminal disclaimer is properly required.

This is a provisional obviousness-type double patenting rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP